REMARKS

This application has been amended in a manner that is believed to place it in condition for allowance.

Status of the Claims

Claims 1, 9, 14 and 15 are amended to address the formal matters raised in the outstanding Official Action.

Support for amendment may be found, for example at specification page 1, lines 20-26, page 3, lines 3-12 and 14-20.

Claims 2-8, 11-13, 16 and 17 are cancelled without prejudice.

Claims 1, 9, 10, 14, and 15 remain pending in the application.

Claim Rejections-35 USC §112

Claims 1-17 were rejected under 35 USC §112, first paragraph, for both not being enabled and not complying with the written description requirement. These rejections are traversed for the reasons discussed below.

Applicant acknowledges with appreciation the Examiner's suggestion that the claims recite "the treatment of exemplified disease conditions" on page 5 of the Official Action. Accordingly, claim 1 is directed to a method for treating a cancer selected from lymphoma and leukemia in a subject suffering thereof.

Therefore withdrawal of these rejections is respectfully requested.

Claims 1-17 were rejected under 35 USC §112, second paragraph, for being indefinite. These rejections are traversed for the reasons discussed below.

Applicant acknowledges with appreciation the Examiner's suggestions for clarifying the claim language. These suggestions have been included in the amended claims.

For example, the claims now define o-ATP in terms of a conventional chemical name, i.e., adenosine-5'-triphosphate-2',3'-dialdehyde, as described in lines 20-26 of page 1 of the specification. Additionally, the adenosine-5'-triphosphate-2',3'-dialdehyde is administered in the form of a pharmaceutical composition, rather than a preparation, as described at specification page 3, lines 14-24.

Therefore, withdrawal of the rejection is respectfully requested.

Claim Rejections-35 USC §102

Claim 1-3 and 9-17 were rejected under 35 USC 102(b) as being anticipated by CORY et al. from PTO-820, ref R("CORY"). This rejection is respectfully traversed for the reasons below.

CORY fails to disclose either lymphoma or leukemia, as acknowledged in the Official Action.

Therefore, withdrawal of the amendment is respectfully requested.

Claim Rejections-35 USC §103

Claims 1-3 and 9-17 were rejected under 35 USC 103(a) as being unpatentable over CORY et al. ("CORY"). This rejection is respectfully traversed for the reasons that follow.

The claimed invention provides unexpected superior results compared to known P2X7 antagonists, as evidenced by the Declaration Under Rule 132 by Maria Elena Ferrero in the appendix of this amendment.

The experimental results discussed in the declaration suggest that the specificity of the o-ATP anti-tumor effect compared to a reference compound that, like oATP, is known to interact with P2X7 nucleotide receptor but, unlike oATP, is unable or much less capable to inhibit endothelial cell proliferation and to induce apoptosis in (i.e., to cause the death of) human promyelocytic leukemia HL60 cells.

In the experimental results, oATP and two P2X7 receptors antagonists (the pyridoxal phosphate-6-azophenil-2',4'-disulphonic acid (PPADS), a non-specific P2X7 antagonist, and 1-(N, O-bis[5-isoquinolinesulphonyl]-N-methyl-L-tyrosyl)-4-phenylpiperazine (KN62), a potent P2X7 antagonist, especially at the human receptor) were tested for their ability to inhibit the proliferation of human umbilical vein endothelial cells (HUVEC)

and to induce apoptosis in a promyelocytic leukemia cell line (HL60). In addition, o-ATP was assayed for its ability to modulate the expression of TNFalpha receptors TNFR1 and TNFR2.

The results illustrated in the Figures included the declaration indicate that:

1) compared to the reference P2X7 antagonists, oATP-induced inhibition of endothelial cell proliferation is significantly higher (Figure 1); neither oATP nor the P2X7 antagonists induce apoptosis in the same cells (Figure 2);
2) oATP down regulates the expression of TNFalpha R1 (Figure 2a);
3) compared to the P2X7 antagonists, oATP-induced apoptosis of HL60 cells is significantly higher (Figures 3 and 4).

The effects described under 10 and 2) are predictive of a higher efficacy of oATP to counteract the angiongenic process, which involves the proliferation of endothelial cells and an inflammatory state caused by TNFalpha, whereas the effects described under 3)are indicative of a higher anti-leukemic effectiveness of oATP compared to P2X7 antagonists.

One of ordinary skill in the art would have expected o-ATP to be able to inhibit to such a large extent endothelial cell proliferation and TNFalpha R1 expressed on the same cells, let alone to induce a pro-apoptotic effect in leukemia cells.

Thus, applicant respectfully submits that the declaration demonstrates oATP effectiveness in the inhibition of leukemia cell proliferation is striking and leaves no doubts about the possibility of using such a compound for the treatment of leukemia as well as lymphoma, more effectively than expected with known P2X7 antagonists.

Moreover, the original article of CORY, e.g., published in 1973 and cited in the IDS August 16, 2006, teaches periodate-oxidase ATP is able to inhibit the ribonucleotide reductase isolated from Ehrlich tumor cells, but it is completely silent about any effect of the same compound on tumor-cell proliferation. In other words, Ehrlich tumor cells are used by CORY as a source of the enzyme ribonucleotide reductase, not as a model for testing the anti-tumor activity of oxidized ATP.

Thus, one skilled in the art would find no guidance/motivation in CORY to use oATP for treating lymphoma or leukemia as presently claimed, even more considering that, as previously noted, the Ehrlich tumor taught by CORY is a murine mammary carcinoma and not a lymphoma as suggested in the Official Action.

Therefore, CORY does not render obvious the claimed invention, and withdrawal of the rejection is respectfully requested.

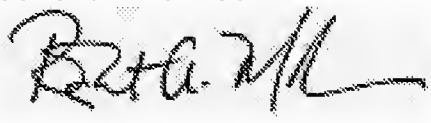
Conclusion

In view of the amendment to the claims and foregoing remarks, therefore, applicant believes that the present application is in condition for allowance at the time of the next Official Action. Allowance and passage to issue on that basis is respectfully requested.

The Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 25-0120 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17.

Respectfully submitted,

YOUNG & THOMPSON



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APPENDIX:

- Declaration of Maria Elena Ferrero, signed January 8, 2009.